



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May XX, 2021

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On behalf of the U.S. Environmental Protection Agency, I am responding to your letter dated April 20, 2021, regarding EPA's registration of Seresto flea and tick collars and EPA's Incident Data System (IDS).

EPA takes its responsibility to protect human health and the environment very seriously and recognizes that pets are part of the family in many American households. The Agency is committed to following the science and the law as we work on the Seresto collar issue.

EPA shares regulatory authority over pet and animal insecticides with the Center for Veterinary Medicine (CVM) of the Food and Drug Administration, with CVM generally responsible for approving animal drugs and regulating flea and tick products that are given orally, including pills, chews, and swallowable liquids, or by injection. EPA, with some exceptions, regulates those products that are applied to pets topically – to pets' skin or fur. This includes shampoos, collars, dust or powder, sprays, and spot-on flea and tick products.

EPA regulates pesticides under the authority of the Federal Insecticide, Fungicide, and Insecticide Act (FIFRA). Section 6(a)(2) of FIFRA requires registrants to submit to the Agency any additional factual information regarding unreasonable adverse effects on the environment of a pesticide after its registration. In evaluating pesticides, EPA must take into account the economic, social, and environmental costs and benefits of the use of any pesticide in determining whether the risk to humans or the environment (including pets) is unreasonable.

After registering a pesticide, EPA receives aggregated incident reports from registrants under FIFRA section 6(a)(2) and some more detailed information for incidents that result in human or domestic animal death or major or minor consequences. These reports, and those acquired from other sources on an ad-hoc basis, are entered into EPA's Incident Data System and reviewed by staff from several Office of Pesticide Program divisions to further understand the incidents and identify potential concerns. EPA

does not require or review pre-market clinical trials under FIFRA but does require a narrowly focused companion animal safety study (OCSP 870.7200) prior to product registration.

Because the data that registrants submit to EPA under the requirements of FIFRA section 6(a)(2) are unconfirmed allegations of adverse reactions (registrants are not required to investigate any adverse reaction reports), in order to properly investigate incidents for regulatory purposes, EPA must obtain this additional information to help better characterize the nature and scale of the incidents reported.

On April 27, 2021, EPA wrote to the current and former Seresto registrants, Elanco and Bayer, respectively, requiring the submission of information needed to further assess the reported incidents. The requested information is substantial and includes:

- annual incident rate stratified by clinical severity and, if possible, collar size/pet type;
- information on Seresto regulation in Canada, the European Union, and globally;
- global pharmacovigilance information on the Seresto collars (the collection, detection, assessment, monitoring, and prevention of adverse effects);
- sales data and enhanced incident data; and
- underlying data supporting analyses of incidents, including those of neurological effects.

Elanco was also asked to provide information supporting its assertions at a March 23, 2021 meeting with EPA that, from 2013 to 2020, the overall annual rate of reported incidents decreased, while the number of Seresto collars distributed in the United States increased; that there is no established link between death and exposure to flumethrin and imidacloprid, the active ingredients in the Seresto collars; and that the incident rate of reported neurological signs in pets is “very rare” and may reflect the background prevalence of seizure/convulsions in pets.

Elanco and Bayer were given 10 days (until May 7, 2021) to respond to EPA in writing with a description of the information they intend to submit to the Agency and must submit that information within 30 days of the date of the letter.

In order to provide more context for understanding the Seresto incidents, EPA has asked Elanco and Bayer for incident rates for their other pet insecticide product lines, including Advantage II and K9 Advantix.

Once EPA receives and reviews the additional information from the Seresto registrants, the Agency will evaluate if the continued registration of these pet collars still meets the FIFRA standard for registration. Upon completing the analysis and assessment, EPA may take further action, if needed.

In contrast to EPA, FDA’s Center for Veterinary Medicine, under the Federal Food, Drug, and Cosmetic Act, has a robust post-market surveillance/pharmacovigilance program and the resources to proactively require and review detailed information on individual incidents, such as the affected animal’s species, sex, age, health status, nature of exposure, clinical signs; comparative sales data for the product involved, and a detailed narrative on the incident that aids in conducting causality assessments. FDA proactively monitors incident trends and signal detection algorithms for early detection of potential safety issues. Two pre-market animal safety and clinical practice studies (VICH GL43 and GL9) allow for a robust product safety review by FDA veterinarians prior to product clearance.

EPA understands the concerns of pet owners who seek to protect their pets from troublesome fleas and ticks and fear that the remedy may be worse than the problem. Since ticks are public health pests – various tick species transmit diseases such as Lyme disease, tick-borne relapsing fever, ehrlichiosis, and Rocky Mountain spotted fever – FIFRA requires EPA to weigh any risks of the pesticide against the benefits of controlling vector-borne diseases.

EPA always encourages consumers to consult with their veterinarian before using any insecticide on their pets and to read and follow all pesticide product labels. Product labels are the law, and they are a vital part of EPA's efforts to ensure that consumers have the information they need to use EPA-registered pesticide products safely, legally, and effectively.

Consumers whose pet experiences an adverse reaction with use of a Seresto pet collar should immediately remove the collar from the pet and contact their veterinarian. They may also contact the [HYPERLINK "https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fnpic.orst.edu%2F&data=04%7C01%7COverbey.Dian%40epa.gov%7C0f31df1b5e1b48aca81c08d909a27306%7C88b378b367484867acf976aacbeca6a7%7C0%7C0%7C637551415593364275%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=aaDIknAMInsK6TPL3wZbYsE3XskUyCs8775ZiaT4i40%3D&reserved=0" \t "_blank"], an EPA information-sharing partner that has staff who are specially trained in responding to pesticide exposure incidents, including those involving pets.

Consumers should also report the incident to EPA at [HYPERLINK "http://www.epa.gov/pets" \t "_blank"]. These reported incidents inform EPA's risk analyses and its decision-making on the product's registration and labeling.

EPA understands the importance of Congress's need to obtain information necessary to perform its legitimate oversight functions, and we are committed to working with your staff to accommodate Congress's interests. Enclosed, please find copies of the letters to Elanco and Bayer along with a second production of documentation responsive to your request. The enclosed information represents individual incident reports for each of the 12 products listed in Appendix A of your letter. We anticipate releasing to you additional information on a rolling basis as it becomes available.

If you have any further questions, please contact me, or your staff may contact Kristien Knapp in EPA's Office of Congressional and Intergovernmental Relations at Knapp.Kristien@epa.gov.

Sincerely,

Radha Adhar
Deputy Associate Administrator

Enclosures

cc: The Honorable Michael Cloud, Ranking Member

Internet Address (URL) - [HYPERLINK "http://www.epa.gov/" \h]